JAN 1 8 2002

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Cholinesterase method for Bayer ADVIA® 1650 System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K013750**

1. Intended Use

The Cholinesterase in vitro diagnostic procedure is intended to measure cholinesterase enzyme activity in human serum, plasma (lithium heparin) on the Bayer ADVIA® 1650 System. Such measurement is used in the diagnosis and treatment of organophosphorus poisoning and certain liver diseases such as cirrhosis, acute and chronic hepatitis.

2. Predicate Device/ Method

Product Name	Reagent Part #	Calibrator Part #	Predicate Device #
Kodak Vitros 250/ Cholinesterase	800 4707	120 4247	K913198, K912217

3. Device / Method

Product Name	REF	Calibrator Part #
ADVIA 1650 / Cholinesterase	B01-4605-01	N/A, (absolute calibration factor 43287)

A. Imprecision

ADVIA 1650 Cholinesterase	
Level (U/L)	Total CV(%)
4235.86	1.1
6978.97	0.9
12318.49	1.1

Kodak Vitros 250 Cholinesterase	
Level (U/L)	Total CV(%)
4350	4.3
6310	4.0

Correlation (Y=ADVIA 1650 Cholinesterase, X= Vitros 250 cholinesterase)

Specimen type	Comparison System (X)	N	Regression Equation	Syx (U/L)	r	Sample Range (U/L)
Serum	Kodax Vitros 250	58	Y=1.325X+228.69	306.57	0.994	1560.0-11090.0
Plasma(Y) vs Serum(X)	ADVIA 1650	40	Y=0.973X+130.33	359.9	0.984	5051.4-14467.1

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Control (U/L)	Test Sample (U/L)	Effect (% change)
Bilirubin (unconjugated)	25	7705.57	7651.71	-0.70
Bilirubin (conjugated)	25	7561.88	7633.48	+0.95
Hemoglobin	520	9659.20	9701.98	+0.44
Lipids (Intralipid)	520	9655.47	9643.34	-0.13

Analytical Range
Serum/Plasma: 1,500 – 30,000 U/L

Nonclinical testing demonstrates that this device is as safe and effective as the predicate device.

Prepared by:

Kenneth T. Edds, Ph.D.
Regulatory Affairs
Bayer Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591

On: January 15, 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 1 8 2002

Kenneth T. Edds, Ph.D.
Manager, Regulatory Affairs
Bayer Diagnostic Corporation
511 Benedict Avenue
Tarrytown, NY 10591-5097

Re: k013750
Trade/Device Name: Cholinesterase Assay for the Advia 1650
Regulation Number: 21 CFR 862.3240
Regulation Name: Cholinesterase Test System
Regulatory Class: Class I
Product Code: DIH
Dated: November 12, 2001
Received: November 13, 2001

Dear Dr. Edds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K013750

Device Name: Cholinesterase Assay for the Advia 1650

Indications for Use:

The ADVIA 1650 Cholinesterase *in vitro* diagnostic procedure is intended to measure cholinesterase in human serum and plasma on the Bayer ADVIA 1650 system. Such measurement is used in the diagnosis and treatment of organophosphorus poisoning and of certain liver diseases such as cirrhosis and acute and chronic hepatitis.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013750

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-CounterUse _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)